

Comments and Responses Regarding Draft Local Coverage Determination Vertebroplasty and Kyphoplasty (Percutaneous)

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Vertebroplasty and Kyphoplasty (Percutaneous) LCD. The official notice period for the final LCD begins on February 14, 2008, and the final determination will become effective on April 1, 2008.

Comment: Several physicians wrote to ask that the six weeks to three months of accepted/conservative medical management prior to vertebroplasty or kyphoplasty not be required for individuals with painful osteoporotic compression fractures. One physician limited his request to those patients who have a second fracture after a successful vertebroplasty or kyphoplasty that was performed for a fracture not responding to conservative treatment. The rationale for more immediate treatment was that the patient, usually elderly, would have more immediate pain relief and not be exposed to complications from analgesics, decreased activity, and bed rest.

Response: Studies are lacking to determine the optimal period of conservative management prior to vertebroplasty or kyphoplasty. However, most have included a period of conservative management. One study¹ sent to us by a commenter was a prospective, consecutive cohort study of patients who underwent kyphoplasty with vertebral compression fractures that were either less than 10 weeks old (acute) or more than 4 months old (chronic). The average time prior to kyphoplasty was 1.1 months for the acute group and 11 months for the chronic. Two weeks after surgery 90% of the acute and 87% of the chronic fracture patients had pain relief. The postoperative use of pain medication was not different between the groups. The Oswestry scores improved for almost all of the patients in each group. There was a significant difference in the amount of fracture reduction in the acute compared to the chronic group.

A second study² sent was a retrospective, single-arm cohort study of consecutive kyphoplasty patients. The authors stated there was no relationship between the fracture age and pain reduction or vertebral body height.

Diamond et al.³ studied patients who presented to the emergency department or were admitted as inpatients with acute vertebral fracture syndrome. Patients had a one to six-week history of incapacitating pain that was not relieved by nonopioid analgesia. Percutaneous vertebroplasty was offered to all meeting the inclusion criteria. Patients who declined served as the control group. The vertebroplasty group had a decreased pain score at rest and with walking compared to the control group 24 hours after the procedure. However, there were no significant differences in pain between the groups at six weeks and six to twelve months. The study was designed to determine the effectiveness of percutaneous vertebroplasty for osteoporotic fractures rather than the period of time for conservative management. However, patients treated with vertebroplasty had six or fewer weeks of conservative treatment prior to the procedure as did the controls who continued to have conservative treatment for six weeks compared to the intervention group.

Given the findings in the literature and the lack of studies of short or no period of conservative management, the policy will state for vertebroplasty and kyphoplasty that one indication is “an osteoporotic compression fracture of the lumbar or thoracic vertebrae with persistent debilitating pain that has not responded to accepted standard medical treatment generally within six weeks to three months.”

Comment: One commenter was concerned about “Utilization Guidelines” proposed for kyphoplasty which limited the procedure to two (2) vertebral levels performed in a single session. He noted that there are jurisdictions in which there would be different utilization guidelines for the carrier and the intermediary.

Response: We confirmed there would be potential discrepancies. The references were reviewed again with an emphasis on number of vertebrae treated. Neither the literature for vertebroplasty or kyphoplasty specifically addressed the issue of number of vertebrae treated per session. Some but not all papers provided information on the number of levels treated.

We will alter the policy to state that for vertebroplasty and kyphoplasty, the contractor would not anticipate more than one to two levels would usually be treated per session. Documentation must be present to justify the treatment of each level.

Comment: Two commenters verbally recommended a bone biopsy be obtained during the procedure.

Response: Coding guidelines for bone biopsy were present in the supplemental instructions article.

Comment: One commenter noted that absolute contraindications to the procedures included retro-pulsed bone fragments and (spinal) canal compromise.

Response: The absolute contraindications have been revised for vertebroplasty and kyphoplasty.

Comment: A request was made to add the office (11) place of service (POS).

Response: We will add office POS since there are some operative settings classified as an office in which these procedures could be performed.

¹ Crandall D, Slaughter D, Hankins PJ, Moore C, Jerman J. Acute versus chronic vertebral compression fractures treated with kyphoplasty: early results. *Spine J* 2004; 4:418-424.

² Majd ME, Farley S, Holt R. Preliminary outcomes and efficacy of the first 360 consecutive kyphoplasties for the treatment of painful osteoporotic vertebral compression fractures. *Spine J* 2005;5:244-255

³ Diamond TH, Champion B, Clark WA. Management of acute osteoporotic vertebral fractures: A nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy. *Am J Med* 2003;114:257-265.